

Independent studies verify the accuracy of the DrugCheck® NxStep OnSite test cup

Express Diagnostics, Int'l Inc. recently commissioned an independent study by Kroll Laboratory Specialists to determine the specificity and accuracy duration of the DrugCheck® NxStep Onsite test cup. As one of the foremost providers of drug testing analysis, Kroll Laboratory Specialists' studies set the standard for test evaluation through the collection of multiple samples and comprehensive statistical data. Following are their results.



SPECIFICITY STUDIES

Introduction

The purpose is to perform specificity studies on DrugCheck® NxStep OnSite test kits utilizing lot numbers 801122706 (expiration June 2008) and 610010307 (expiration July 2008). Lot number 801122706 tests for Benzodiazepines (BNZ), Opiates (OPI 300), Methadone (MDN), Methylene dioxy-methamphetamine (MDMA), Oxycodone (OXY), Propoxyphene (PPX), and Tricyclic antidepressants (TCA). Lot number 610010307 tests for Amphetamines (AMPHS), Methamphetamine (MAMP), Benzoylcegonine (BE), Tetrahydrocannabinoids (THC), and Phencyclidine (PCP). The testing was performed between 1/9/07 and 1/25/07 at Kroll Laboratory in Gretna, LA.

Materials and Methods

In the specificity studies, the test kits were exposed to a minimum of twenty positive patient samples at various levels based on GC/MS. The cups were then read as soon as readable results were possible. All samples were initially screened by CEDIA or DRI immuno assay and confirmed by Gas Chromatography/Mass Spectroscopy. The chemist performing the test was trained in the interpretation of on-site test results. All questionable samples were subjected to a second screening analysis with either CEDIA or DRI reagents.

DATA

OPI300 OPI OPI OPI Specificity Lot 801122706

Sample	Confirmed	Result
1. 2131143	Mor 574	Positive OPI
2. 2130925	Mor 712	Positive OPI
3. 2131295	Mor 565	Positive OPI
4. 2139146	Mor 754	Positive OPI
5. 2178624	Mor 639	Positive OPI
6. 2206217	Mor 547	Positive OPI
7. 2206218	Mor 763	Positive OPI
8. 2131869	Mor 249	Negative OPI
9. 2152617	Mor 242	Negative OPI
10. 2131044	Cod 383	Positive OPI
11. 2131115	Cod 4921	Positive OPI
12. 2131147	Mor 1579	Positive OPI
13. 2131422	Mor 57499	Positive OPI
14. 2130814	Oxy 2124	Negative OPI
15. 2127627	Hyc 1202	Positive OPI
16. 2127924	Cod 2566	Positive OPI
17. 2146421	Oxy 565	Negative OPI
18. 2146980	Mor 2243	Positive OPI
19. 2131242	Hyc 963	Positive OPI
20. 2131862	Mor 3288	Positive OPI
21. 2131125	Cod 4921	Positive OPI
22. 2130742	Cod >5000	Positive OPI
23. 2134827	Cod 1035	Positive OPI
24. 2132263	Cod 92480	Positive OPI

OPI2000 OPI OPI OPI Specificity Lot 610010307

	Sample	Screening	Confirmed	Result
1	1876939	>10,000 165	Cod = 323 Mor = 5520 THC = 93	Positive Positive THC
2	1877370	5205	Mor = 3562	Positive
3	1877553	>10,000	Cod = 2669 Mor = 620	Positive
4	1877642	3680	Mor = 3562	Positive
5	1877657	>10,000	Mor = 473	Positive
6	1888935	2525	Cod = 275 Mor = 217	Positive
7	1890188	>40,000	Mor = 69001	Positive
8	1891172	5383	Mor = 2102	Positive
9	1891703	31530	Mor = 12523	Positive
10	1892517	4071	Mor = 2267	Positive
11	1892608	6230	Mor = 6960	Positive
12	1893325	>10,000	Hycd = 4631 Hymr = 1167	Positive
13	1901302	5780 180	Cod = 400 THC = 77	Positive Positive THC
14	1905378	5035	Mor = 3778	Positive
15	1905386	13200	Mor = 5267	Positive
16	1845505	22925	Mor = 7413	Positive
17	1874604	>10,000	Hymr = 2496	Positive
18	1906882	>10,000 >500 603	Cod = 1181 Mor = 340 THC = >2000 Be = 429	Positive Positive THC Positive Be

PROP PPX PPX PPX PPX
Specificity Study Lot 801122706

Sample	Confirmed	Result
1. 1844377	1402	Positive
2. 1844904	7487	Positive
3. 1845807	4352	Positive
4. 1903483	7913	Positive
5. 1903918	2591	Positive
6. 1903947	3793	Positive
7. 2019791	935	Positive
8. 1901595	5821	Positive
9. 1907519	1532	Positive
10. 1907873	>10000	Positive
11. 1911610	3590	Positive
12. 1915317	11676	Positive
13. 2102920	>1000	Positive
14. 2014312	>1000	Positive
15. 2013455	5386	Positive
16. 2014458	6003	Positive
17. 2018932	4126	Positive
18. 2020309	4106	Positive
19. 2020451	7133	Positive
20. 2021727	>10000	Positive

MDN MTD MTD MTD MTD
Specificity study LOT 801122706

Sample	Confirmed	Confirmed	Result
1. 1844644	EDDP >40000	MDN 20378	Positive
2. 2014143		MDN >500	Positive
3. 1890400	EDDP 9931	MDN 3853	Positive
4. 1890836	EDDP 325	MDN >500	Positive
5. 1890845	EDDP 10679	MDN >10000	Positive
6. 1891127	EDDP 4394	MDN 6783	Positive
7. 1906815	EDDP 7021	MDN 6177	Positive
8. 1907008	EDDP 798	MDN >500	Positive
9. 1907566		MDN >500	Positive
10. 1907626	EDDP >800	MDN >500	Positive
11. 1915791	EDDP 10321	MDN >10000	Positive
12. 1916073	EDDP 527	MDN 493	Positive
13. 1916111	EDDP 12121	MDN >10000	Positive
14. 1916274	EDDP 389	MDN >500	Positive
15. 1916342	EDDP 7611	MDN >500	Positive
16. 1917098		MDN >500	Positive
17. 2012686	EDDP >16000	MDN >10000	Positive
18. 3007597	EDDP 1520	MDN 313	Positive
19. 2019557	EDDP >16000	MDN >10000	Positive
20. 2018765	EDDP >800	MDN >500	Positive

** Both of these samples are being re-analyzed by GC/MS to determine if degradation of the Benzodiazepines resulted in the negative reading with the on-site testing device.

Oxycodone OXY OXY OXY OXY
Specificity study LOT 801122706

Sample	Conformation	Result
1. 2130814	2124	Positive
2. 2146421	565	Positive, F
3. 2146586	273	Positive, F
4. 2151562	4958	Positive
5. 2151995	2028	Positive
6. 2152443	4835	Positive
7. 2152536	3584	Positive
8. 2151446	513	Positive
9. 2152198	551	Positive, F
10. 2123839	8189	Positive
11. 2124604	2264	Positive
12. 2156988	470	Positive
13. 2161794	2782	Positive
14. 2160995	910	Positive, F
15. 2173837	1764	Positive
16. 2173946	583	Positive
17. 2174358	2965	Positive
18. 2190018	3919	Positive
19. 2190849	1395	Positive
20. 2191343	3678	Positive

BENZ BZD BZD BZD BZD
Specificity Study LOT 801122706

Sample	Conformation	Conformation	Result	Re-screen
1. 201943	APAM 374		Positive	
2. 2011942	NPAM 332		Positive	
3. 2011938	APAM 520		Positive	
4. 201939	OPAM 173		Negative	<Cut Off
5. 201960	OPAM 563	TPAM 677	Positive	
6. 201949	APAM 314		Positive	
7. 201947	OPAM 563		Negative	889**
8. 201946	OPAM >50000		Positive	
9. 1844602	APAM >1000		Positive	
10. 1844946	OPAM 449		Positive	
11. 201953	NPAM 195	OPAM 569	Positive	
12. 1891155	TPAM 651		Positive	
13. 1876471	OPAM >1000		Positive	
14. 1876556	APAM 6334		Positive	
15. 201954	OPAM 449	TPAM 807	Positive	
16. 1840134	APAM 309		Positive	
17. 1873942	APAM 451		Positive	
18. 3470267	OPAM 303		Positive	
19. 3472351	OPAM 842	TPAM >2500	Negative	973**
20. 3471559	OPAM 735	TPAM 311	Positive	

MAMP MET MET MET MET
Specificity Lot 610010307

	Sample	Screening	Confirmed	Result
1	1891978	2830	Amp=>200 Mamp=1875	Positive
2	1901691	2805	Amp=260 Mamp=1799	Positive
3	1893055	4985	Amp=1163 Mamp=2827	Positive
4	1877191	11700	Amp=20588 Mamp=1284	Positive
5	1891174	1051	Amp>200 Mamp=598	Positive
6	203292	>25000	Amp=2794 Mamp=7842	Positive
7	203299	1718	Amp=582 Mamp=521	Positive
8	1890564	2223	Amp=365 Mamp=1021	Positive
9	1906326	1599	Amp=357 Mamp=783	Positive
10	1891157	3615 >500	Amp=768 Mamp=3128 THC=492	Positive Positive THC
11	1906355	2820	Amp=813 Mamp=1649	Positive
12	1906619	>25000	Amp=19802 Mamp=>100000	Positive
13	1906785	3006	Amp=284 Mamp=1489	Positive
14	1906819	2350	Amp=1072 Mamp=1546	Positive
15	1891708	2130	Amp=853 Mamp=1222	Positive
16	2049376	4565	Amp=1085 Mamp=1277	Positive
17	2049837	3180	Amp=342 Mamp=1264	Positive
18	2049880	2326	Amp=433 Mamp=975	Positive
19	2050012	21085	Amp=2231 Mamp=>10000	Positive
20	2050134	1291 492	Amp>200 Mamp=853 Be=492	Positive Positive Be
21	2050222	1752	Amp=507 Mamp=1246	Positive
22	1904495	>25000	Amp=23931 Mamp=>100000	Positive

AMP
Specificity Lot 610010307

	Sample	Screening	Confirmed	Result
1	1405001	2300	Amp = 1498	Positive
2	1889458	8215	Amp = 9108	Positive
3	1890741	13715	Amp = >10000	Positive
4	1891688	1340	Amp = 1533	Positive
5	1891689	8935	Amp = 9220	Positive
6	1844762	1552	Amp = 1900	Positive
7	1844918	2494	Amp = 4172	Positive
8	2052790	1324	Amp = 1647	Positive
9	2052814	2545	Amp = 4394	Positive
10	2046113	3512	Amp = 6404	Positive
11	2046220	1345	Amp = 2169	Positive
12	1903882	>100000	Amp = 7545	Positive
13	1904374	1970	Amp = 2340	Positive
14	1905151	3149	Amp = 5888	Positive
15	1875438	2162	Amp = 3577	Positive
16	1845264	4715	Amp = 6927	Positive
17	1845427	15025	Amp = >10000	Positive
18	1872439	3140	Amp = 4694	Positive
19	1874508	1524	Amp = 2354	Positive
20	1874516	4006	Amp = 9682	Positive

THC
Specificity Lot 610010307

	Sample	Screening	Confirmed	Result
1	203067	61	THC = 31	Positive
2	203063	135	THC = 81	Positive
3	2046415	84	THC = 39	Positive
4	2046430	58	THC = 34	Positive
5	2044944	85	THC = 39	Positive
6	2045336	135	THC = 66	Positive
7	2045513	93	THC = 74	Positive
8	2045514	63	THC = 36	Positive
9	2045518	58	THC = 34	Positive
10	2045534	73	THC = 33	Positive
11	2045571	>500	THC = 753	Positive
12	2045703	92	THC = 148	Positive
13	2046111	87	THC = 43	Positive
14	2045706	91	THC = 119	Positive
15	204241	42	THC = 22	Positive
16	204399	75	THC = 22	Positive
17	204259	180	THC = 89	Positive
18	1838837	>500	THC = 839	Positive
19	2046141	84	THC = 45	Positive
20	2046686	52	THC = 32	Positive

Be
Specificity Lot 610010307

	Sample	Screening	Confirmed	Result
1	2045475	317	Be = 243	Positive
2	2045507	923	Be = 854	Positive
3	2045513	374	Be = 285	Positive
4	2045591	744	Be = 679	Positive
5	2045385	510	Be = 394	Positive
6	2045202	605	Be = 603	Positive
7	2044944	>25000	Be = 161932	Positive
8	1844461	327	Be = 245	Positive
9	1844476	645	Be = 449	Positive
10	1844642	447	Be = 476	Positive
11	1844643	330	Be = 384	Positive
12	1844461	327	Be = 245	Positive
13	1844720	590	Be = 555	Positive
14	1844787	821	Be = 725	Positive
15	1845249	431	Be = 292	Positive
16	2043382	337	Be = 376	Positive
17	1933567	897	Be = 700	Positive
18	1844127	732	Be = 734	Positive
19	1844130	1047	Be = 1001	Positive
20	1844248	386	Be = 394	Positive

PCP
Specificity Lot 610010307

	Sample	Screening	Confirmed	Result
1	216652	355 380	PCP = 373 THC = 163	Positive
2	3229701	59 >500	PCP = 51 THC = 317	Positive
3	3215326	236 87	PCP = 324 THC = 41	Positive
4	3224207	405 455	PCP = 359 THC = 272	Positive
5	3224898	188 215 >25000	PCP = 201 THC = 110 Be = 99508	Positive
6	3218906	226	235	Positive
7	3216453	>750	>1000	Positive
8	3220640	61	48	Positive
9	3220377	53	53	Positive
10	3215184	64	56	Positive
11	3208690	64	49	Positive
12	3222740	52	47	Positive
13	PCP 1	522	533	Positive
14	PCP 2	258 >3000	PCP = 229 Be = >3000	Positive
15	PCP 3	11884 1380	PCP = 97 THC = 1381	Positive
16	PCP 4	229	PCP = 200	Positive
17	PCP 5	54 742	PCP = 45 Be = 661	Positive
18	PCP 6	125	PCP = 101	Positive

Discussion

The specificity trials for Propoxyphene and Methadone returned positives above the stated cutoff across a wide range. The results were easy to read.

The specificity trial for Oxycodone returned positives above the stated cutoff. A few of the samples approaching the stated cutoff of 100 ng/mL appeared to have a very faint line present in the negative line area. Upon casual inspection the samples appeared positive, but upon close scrutiny, the samples may appear to test negative. The samples are designated with an "F" in the result column.

The specificity trial for BENZ returned positives on all of the samples above the stated cutoff off 300 ng/mL except for two samples. The two samples that returned negative results were rescreened. The rescreen results were above the stated cutoff for both samples. Both of the negative samples > cut off are being re-analyzed by GC/MS to determine if degradation created the negative on-site test result. On the positive results, oxazepam and alpha-hydroxyalprazolam very near the cutoff returned good positives. The third negative result confirmed positive, but was under the stated cutoff, so a negative result was expected from this sample.

The kits performed at an overall accuracy rate of 98.2%. The performance on THC, Cocaine, PCP, Amphetamine, Methamphetamine and OPI2000 was 100%. Several samples were run below the stated cut off and did return the expected negative result. The kits were easy to handle and interpret.



Pat Pizzo, Director of Toxicology
Kroll Laboratory Specialists

TIMED TRIALS

Introduction The purpose is to perform time trials on DrugCheck® NxStep OnSite test kits utilizing lot numbers 801122706 (expiration June 2008) and 610010307 (expiration July 2008). Lot number 801122706 tests for Benzodiazepines (BNZ), Opiates (OPI 300), Methadone (MDN), Methylene dioxy-methamphetamine (MDMA), Oxycodone (OXY), Propoxyphene (PPX), and Tricyclic antidepressants (TCA). Lot number 610010307 tests for Amphetamines (AMPHS), Methamphetamine (MAMP), Benzoylcegonine (BE), Tetrahydrocannabinoids (THC), and Phencyclidine (PCP). The testing was performed between 1/9/07 and 1/25/07 at Kroll Laboratory in Gretna, LA.

Materials and Methods In the time trials, six to ten test kits were exposed to positive patient urine at a level approximately two times the stated cutoff based on GC/MS results, certified negative urine and actual donor samples were used for the study. All samples were initially screened by CEDIA or DRI immuno assay and confirmed by Gas Chromatography/Mass Spectroscopy. The chemist performing the test was trained in the interpretation of on-site test results. All questionable samples were subjected to a second screening analysis with either CEDIA or DRI reagents.

DATA

Negative timed study with lot 801122706

Sample	5 minutes	30 minutes
1. Negative Lot# 88	Negative	Negative
2. Negative Lot# 88	Negative	Negative
3. Negative Lot# 88	Negative	Negative
4. Negative Lot# 88	Negative	Negative
5. Negative Lot# 88	Negative	Negative
6. Negative Lot# 88	Negative	Negative
7. Negative Lot# 88	Negative	Negative
8. Negative Lot# 88	Negative	Negative
9. Negative Lot# 88	Negative	Negative
10. Negative Lot# 88	Negative	Negative

Negative timed study with lot 610010307

Sample	5 minutes	30 minutes
1. Negative Lot# 88	Negative	Negative
2. Negative Lot# 88	Negative	Negative
3. Negative Lot# 88	Negative	Negative
4. Negative Lot# 88	Negative	Negative
5. Negative Lot# 88	Negative	Negative
6. Negative Lot# 88	Negative	Negative
7. Negative Lot# 88	Negative	Negative
8. Negative Lot# 88	Negative	Negative
9. Negative Lot# 88	Negative	Negative
10. Negative Lot# 88	Negative	Negative

Discussion

Both lots performed as expected in the timed trials with the negative lot.

The time trials for THC, BE, AMPHS, and MAMP with lot 610010307, tested as expected. The results

THC timed study lot 610010307

Sample	Confirmation	5 minutes	30 minutes
1. THC 2132197	87	Positive	Positive
2. THC 2132203	86	Positive	Positive
3. THC 2131130	72	Positive	Positive
4. THC 2134930	74	Positive	Positive
5. THC 2133127	76	Positive	Positive
6. THC 2132422	79	Positive	Positive
7. THC 2131971	83	Positive	Positive

THC timed study with lot 801122706

Sample	Confirmation	5 minutes	30 minutes
1. THC 2132197	87	negative	negative
2. THC 2132203	86	negative	negative
3. THC 2131130	72	negative	negative
4. THC 2134930	74	negative	negative
5. THC 2133127	76	negative	negative
6. THC 2132422	79	negative	negative
7. THC 2131971	83	negative	negative

Be timed study lot 610010307

Sample	Confirmation	5 minutes	30 Minutes
1. BE 2128513	837	Positive	Positive
2. BE 2131153	621	Positive	Positive
3. BE 2130813	559	Positive	Positive
4. BE 2132143	649	Positive	Positive
5. BE 2132215	542	Positive	Positive
6. BE 2135863	594	Positive	Positive
7. BE 2135616	584	Positive	Positive

Be timed study with lot 801122706

Sample	Confirmation	5 minutes	30 Minutes
1. BE 2128513	837	negative	negative
2. BE 2131153	621	negative	negative
3. BE 2130813	559	negative	negative
4. BE 2132143	649	negative	negative
5. BE 2132215	542	negative	negative
6. BE 2135863	594	negative	negative
7. BE 2135616	584	negative	negative

were easy to read and did not change over time. The time trial for lot 801122706 tested as expected. The results were easy to read and did not change over time. The kits performed at an overall accuracy rate of 100% at both 5 and 30 minutes.

AMPHS timed study lot 610010307

Sample	Confirmation	5 Minutes	30 Minutes
1. AMPHS 2129583	2453	Positive	Positive
2. AMPHS 2131827	2417	Positive	Positive
3. AMPHS 2133282	2548	Positive	Positive
4. AMPHS 2134385	2029	Positive	Positive
5. AMPHS 2131994	2056	Positive	Positive
6. AMPHS 2148944	1933	Positive	Positive
7. AMPHS 2132172	2719	Positive	Positive

AMPHS timed study with lot 801122706

Sample	Confirmation	5 Minutes	30 Minutes
1. AMPHS 2129583	amp 2453	negative	negative
2. AMPHS 2131827	amp 2417	negative	negative
3. AMPHS 2133282	amp 2548	negative	negative
4. AMPHS 2134385	amp 2029	negative	negative
5. AMPHS 2131994	amp 2056	negative	negative
6. AMPHS 2148944	amp 1933	negative	negative
7. AMPHS 2132172	amp 2719	negative	negative

MAMP timed study 610010307

Sample	Confirmation	5 minutes	30 Minutes
1. MAMP 2134918	2353	Positive	Positive
2. MAMP 2135563	2293	Positive	Positive
3. MAMP 2151242	1903	Positive	Positive
4. MAMP 2132037	1491	Positive	Positive
5. MAMP 2153642	5043	Positive	Positive
6. MAMP 2131870	1132	Positive	Positive

MAMP timed study with lot 801122706

Sample	Confirmation	5 minutes	30 Minutes
1. MAMP 2134918	mamp 2353	negative	negative
2. MAMP 2135563	mamp 2293	negative	negative
3. MAMP 2151242	mamp 1903	negative	negative
4. MAMP 2132037	mamp 1491	negative	negative
5. MAMP 2153642	mamp 5043	negative	negative
6. MAMP 3426136	mamp 1974	negative	negative

OPI300 timed study

Sample	Confirmation	5 Minutes	30 Minutes
1. 2131143	Mor 574	Positive OPI	Positive OPI
2. 2130925	Mor 712	Positive OPI	Positive OPI
3. 2131295	Mor 565	Positive OPI	Positive OPI
4. 2139146	Mor 754	Positive OPI	Positive OPI
5. 2178624	Mor 639	Positive OPI	Positive OPI
6. 2206217	Mor 547	Positive OPI	Positive OPI
7. 2206218	Mor 763	Positive OPI	Positive OPI


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